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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/026,021	12/21/2001	Yasumichi Hitoshi	021044-001210US	6123

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EXAMINER	
YU, MISOOK	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 06/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/026,021	HITOSHI ET AL.	
	Examiner	Art Unit	
	MISOOK YU, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 January 2006 and 21 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34 and 36-39* is/are pending in the application.

4a) Of the above claim(s) *1-8,12-14,17,19 and 39* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-11, 15, 16, 18, 20-34, 36-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 26, 2006 and March 21, 2006 has been entered.

Claims 1-8 and 39 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Claims 12-14, 17, 19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim.

Claims 1-34 and 36-39 are pending, and claims 9-11, 15, 16, 18, 20-34, and 36-38 are examined on merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

Claims 9-11, 24, 25, 32, 36, and 37 are rejected under 35 U.S.C. 102(e) as being anticipated by WO 01/53312 A1 (filing date of 26 December 2000, the entire sequence listing and sequence table are not provided in this office action because the document is

over 600 pages. The relevant sequence is provided with the sequence alignments as Exhibits B, and C).

Claims 9-11, 24, 25, 32, 36, and 37 are drawn to method of identifying a useful compound by determining the functional effect of said compound modulating cellular proliferation when said compound is contacted with a SAK polypeptide encoded by a nucleic acid encoding a SAK polypeptide having at least 95% sequence identity to instant SEQ ID NO:2 protein, wherein the polypeptide has serine/threonine kinase activity, wherein the effect is measure in vitro (claim 10), the effect being a physical effect (claim 11), the modulation being inhibition of cellular proliferation (claim 24), inhibition of cancer cell proliferation (claim 25), the polypeptide being used in the method is recombinant (claim 32), the compound being screened in the method is a small organic molecule 9claim 36), and he compound being screened in the method is a peptide (claim 37).

Applicant argues that the amended claim 9 sets forth the language of identifying of compound that modulates cellular proliferation in the body and the preamble of the claim.

This argument has been fully considered but found unpersuasive because a part of the instantly claimed screening method encompasses the screening method of the prior art of record. One part of the claimed method is to identify a compound binding to a SAK polypeptide as the compound modulates cellular proliferation. Claim 9 step (ii) says that any compound that has "a functional effect" upon the polypeptide is the compound that modulates cellular proliferation, and the specification at paragraph

[0010] discloses, "the functional effect is determined by measuring ligand or substrate binding to the polypeptide." This indicates that the base claims are broadly drawn to method of screening a compound binding to the polypeptide and call it a compound modulates cellular proliferation. In other words, the claimed invention encompasses the screening method of the prior art of record both screening methods comprise contacting the same polypeptide with a compound and determine whether the compound has a functional effect, which is binding to the polypeptide. As stated in the previous Office action, WO 01/53312 A1 teaches (1) a SAK polypeptide that is 99.9% identical (i.e. SEQ ID NO: 2389) to the instant SEQ ID NO:2 (see previously provided Exhibit B) encoded by a recombinant nucleic acid (i.e. SEQ ID NO: 603) that is 99.9 % identical to instant SEQ ID NO:1 (see previously provided Exhibit C); (2) drug screening assays by isolating compounds that binds to a polypeptide encoded by the many disclosed recombinant nucleic acids, one of the being SEQ ID NO: 603 (see pages 89-91). Thus, the instant claims 9-11, 18, 24, 25, 32, 36, and 37 read on the drug screening assay of WO 01/53312 A1, which teaches a SAK polypeptide.

Claim Rejections - 35 USC § 103

Claims 9, 15, 16, 18, 26-31, and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 01/53312 A1 (Tang, cited above) in view of US 5,650,501 A of record.

Claims 9, 15, 16, 18, 26-31, and 34 are drawn to method of identifying a useful compound by determining the functional effect of said compound modulating cellular proliferation when said compound is contacted with a SAK polypeptide encoded by a

nucleic acid encoding a SAK polypeptide having at least 95% sequence identity to instant SEQ ID NO:2 protein, wherein the polypeptide with serine/threonine kinase activity is expressed in a eukaryotic host cell (claim 15), the effect being a physical effect (claim 16), a phenotypic effect (claim 18), the host cell being a cancer cell (claim 26, and 27), the cell being transformed cell lines (claims 28, and 30), and the cancer cells being p53 mutant or wild-type (claims 30, and 31), the compound being antibody (claim 34).

Applicant argues that Tang discloses the claimed sequence but does not teach or suggest any method of using the sequence for identifying a compound that modulates cellular proliferation; the 501 patent does not teach the limitation of "a SAK polypeptide having at least 95% sequence identity to SEQ ID NO:2", i.e. the sequence in the patent is less than 80%, which is beyond the ambit of what U.S. Patent Office would consider enabled under 112.

This argument has been fully considered but found unpersuasive. One of ordinary skill in the art based on the disclosures of the two references would be able to make and use the polypeptide within the gambit of the instantly claimed sequence without encountering enablement issue because the '501 patent at Fig. 4 teaches that in order to be a kinases the entire sequences do not have to match 95% or beyond. Rather, the sequence alignment shows that there are several critical residues in each of the kinases. Since the sequence disclosed in Tang has about 80 % sequence identity to the Sak kinase disclosed in the '501 patent, one of ordinary skill would arrive at the conclusion that the sequence disclosed in Tang is a Sak kinase.

Claims 9, 15, and **20-23** are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 01/53312 A1 (cited above) in view of US 5,650,501 A of record and further in view of US 5,959,081 A of record (the '081 patent).

Claims 9, 15, and 20-23 are drawn to method involving measuring cellular proliferation as the functional effect to identify a useful compound by determining whether or not said compound modulates cellular proliferation, when said compound is contacted with a SAK polypeptide having at least 95% sequence identity to the instant SEQ ID NO:2 protein, wherein said cellular proliferation is determined by measuring DNA synthesis or measuring green fluorescent protein.

Applicant argues that there is no motivation or suggestion to further include the disclosure of the '081 because it does not disclose or suggest anything about serine/threonine kinases in general or SAK kinases in particular.

These arguments have been fully considered but found unpersuasive because the importance of SAK kinase in modulating cellular kinase was taught in the '502 patent, thus one of ordinary skill would be motivated using the protein for screening a therapeutically useful compound by measuring DNA synthesis by detecting an amount of ^{3}H thymidine incorporation or measuring green fluorescent protein detection with a reasonable expectation of success, given that the '501 patent teaches that a SAK protein is involved in cellular proliferation, and also given that WO 01/53312 A1 teaches a SAK polypeptide having at least 95% sequence identity to the instant SEQ ID NO:2 protein. One of ordinary skill would be motivated to identify a compound that dilutes the green emission as an candidate that might be inhibiting cellular protein, or the

compound that inhibits ^{3}H thymidine incorporation in DNA of the cell as a possible candidate for inhibiting cancer cell growth because finding such compound would lead to making money.

Claims 9, 37, and **38** are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 01/53312 A1 (cited above) in view of US 5,650,501 A (22 July 1997) and further in view of US 5,589,356 A (31 December 1996, the '356 patent from now on).

Claims 9, 37, and 38 are interpreted as drawn to method of identifying a useful circular peptide by determining whether or not said circular peptide affecting cellular proliferation when said compound is contacted with a SAK polypeptide encoded by a nucleic acid hybridizes under stringent conditions to the nucleic acid encoding the instant SEQ ID NO:2 protein.

Applicant argues that the '501 patent and the '356 patent, alone or combined, do not disclose or suggest a method for identifying a compound that modulates cellular proliferation by contacting a polypeptide having at least about 95% sequence identity to SEQ ID NO:2.

The argument has been considered fully but found unpersuasive because WO 01/53312 A1 teaches the claimed polypeptide being used in the assay, and the '501 patent teaches SAK polypeptides are involved in cellular proliferation, and it is a good idea to use SAK polypeptides to screen a compound because it might lead to identifying a compound to treat cancer. See 102(b) and 103 (a) rejections above for further detail.

Neither WO 01/53312 A1 nor the '501 patent does not teach a circular peptide.

However, the '356 patent teaches (at the front page) a circular peptide and also teach that a usefulness of a circular peptide as a therapeutic has been recognized in the art before the effective filing date of the instant application (note column 3, lines 3-4).

Therefore, it would have been obvious to one of ordinary skill in the art to add a circular peptide to see whether the circular peptide modulates cellular proliferation, given that the '501 patent teaches that a SAK protein is involved in cellular proliferation and WO 01/53312 A1 teaches a SAK polypeptide that meets the amended limitation and the '356 patent teaches many circular peptides. One of ordinary skill in the art would have been able to accomplish the claimed method with a reasonable expectation of success, because WO 01/53312 A1 teaches a SAK polypeptide that meets the amended limitation. One of ordinary skill would have been motivated to screen a circular peptide with the art-known detection methods as described by the '501 paten, given that the '356 patent teaches that a circular peptide might be a candidate therapeutic.

Allowable Subject Matter

Claim 33 is objected because it depends on the rejected base claim. If the scope of the claimed invention using the product of claim 33 the scope of the base claim 9 to SEQ ID NO: 1, then the claims would be allowable.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 571-

272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MISOOK YU, Ph.D.
Primary Examiner
Art Unit 1642